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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,085	08/07/2008	Lionel Bueno	BKR.105	1152

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EXAMINER	
SRIVASTAVA, DEVESH	
ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
01/13/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

euspto@slspatents.com

Office Action Summary	Application No.	Applicant(s)	
	10/586,085	BUENO, LIONEL	
	Examiner	Art Unit	
	DEVESH SRIVASTAVA	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/13/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

The present application is a National Stage filing of PCT/FR2005/000108, filed 1/18/2005, and claims benefit of French application 0400446, filed 1/19/2004, the certified original language copy of which has been received.

Status of Claims

Claims 1-17 have been canceled in a preliminary amendment filed June 10, 2008. Claims 18-34 are newly added.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 18-20, 24-29 and 30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Makovec et al. (WO 02/070468 A2, published September 12, 2002).

3. Makovec et al. disclose the use of chemical compounds, which are inhibitors of metalloproteases (page 2, lines 14-16), for a method of treating pathological conditions of the gastrointestinal system, ulcerative colitis, Crohn's disease, Irritable Bowel Syndrome, food allergies and intolerance (page 4, lines 7-9). This disclosure anticipates **claims 18, 19, 20, 27 and 28**. As hyperalgesia (distension) is a byproduct of these conditions (see page 2, lines 17-20 of instant application), and since these protease inhibitors would necessarily control or reduce paracellular permeability of the intestinal epithelium, **Claims 24 and 25** are also anticipated.

Similarly, these protease inhibitors would necessarily reduce sensitivity to pain (**Claim 26**). Administration of an inhibitor of metalloprotease would necessarily reap the benefits claimed in claims 24-28. Makovec et al. discloses both oral and rectal routes of administration (page 4, line 4; **Claim 29**).

4. Similarly, **Claims 30-31** are also anticipated as hyperalgesia occurring in the context of intestinal pathologies would also be found in the patient populations disclosed by Makovec et al. having a pathological condition of the GI system, ulcerative colitis, Crohn's disease, Irritable Bowl Syndrom or food allergies and intolerance (page 4, lines 7-9).

5. Claims 18-19, 23-29 and 30 are anticipated by Arditi et al. (US 2003/0138423 A1, published July 24, 2003).

6. Arditi et al. disclose the use of protease inhibitors to treat inflammatory conditions of the GI tract, including inflammatory bowel disease, ulcerative colitis and Crohn's Disease [0015] [0033] (**Claims 18, 19 & 27**), which also include functional intestinal disorders (**Claim 28**). The protease inhibitors for treating these conditions include amprenavir, indinavir, lopinavir, ritonavir, saquinavir and nelfinavir [0028] (**Claim 23**). As hyperalgesia (distension) is a byproduct of these conditions (see page 2, lines 17-20 of instant application), and since these protease inhibitors would necessarily control or reduce paracellular permeability of the intestinal epithelium, **Claims 24 and 25** are also anticipated. Similarly, these protease inhibitors would necessarily reduce sensitivity to pain (**Claim 26**). The protease inhibitor may be administered orally (**Claim 29**). Similarly, **Claim 30** is anticipated as hyperalgesia occurring in the context of intestinal pathologies would also be found in the patient populations disclosed by Arditi et al.

having an inflammatory condition of the GI tract, inflammatory bowel disease, ulcerative colitis or Crohn's Disease [0015][0033].

7. Claims 18-22, 24-29, 30-31 are anticipated by EP 0 958 833 A1, published November 24, 1999.

8. The '833 Patent Application discloses the use of protease inhibitors to treat inflammatory conditions of the intestine [0010] (**Claim 18**). The protease inhibitors act on metallo-proteinases aminopeptidases and serine proteinases [0018] found in the intestine or colon [0020] (**Claims 19, 20 and 22**). These protease inhibitors include soy bean extracts [0019] and ovomucoid [0047] (**Claim 21**). As hyperalgesia (distension) is a byproduct of these conditions (see page 2, lines 17-20 of instant application), and since these protease inhibitors would necessarily control or reduce paracellular permeability of the intestinal epithelium, **Claims 24 and 25** are also anticipated. Similarly, these protease inhibitors would necessarily reduce sensitivity to pain (**Claim 26**). The conditions treated are functional intestinal disorders [0013] (**Claim 27**). The conditions include treatment of food intolerance [0020] (**Claim 28**). The treatment can be administered orally [0014] (**Claim 29**). **Claims 30-31** are also anticipated as hyperalgesia occurring in the context of intestinal pathologies would also be found in the patient populations disclosed in the '833 Patent Application and would necessarily be treated in the course of application of the methods disclosed therein.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 32-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Gao et al. (US Patent Application Publication No. 2004/0197411 A1, filed December 18, 2003).

11. Gao et al. disclose a pharmaceutical composition comprising at least one protease inhibitor, a HIV protease inhibitor or matrix metalloproteinase inhibitors, together with gastric cytoprotectants, gastric proton pump inhibitors, gastroprokinetics, anticholinergics, antidiarrheal agents or laxatives or combinations thereof [0002][0026] (**Claims 32 and 33**). Such drugs are useful in the treatment of Crohn's disease, gastritis, irritable bowl syndrome, inflammatory bowel disease and ulcerative colitis [0058]. The composition can be formulated into a capsule [0042] (**Claim 34**).

Conclusion

Claims 18-34 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEVESH SRIVASTAVA whose telephone number is (571) 270-3288. The examiner can normally be reached on Monday - Friday 8:00 - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DEVESH SRIVASTAVA/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner
Art Unit 1615